

## **Hitachi and Axcelead DDP Launch Manufacturing Process Development Support Service for Cell Therapy and Gene Therapy**

Supporting optimization of product development and manufacturing with automation and quality assessment

**Tokyo, December 15, 2021** --- Hitachi, Ltd. (TSE:6501, "Hitachi") and Axcelead Drug Discovery Partners Inc. ("Axcelead DDP") announced today that they launch a manufacturing process development support service for cell therapy and gene therapy from December 16.

This service enables evaluation of cell quality such as stability and biological equivalence, and optimization of the automated cell culture process by combining Hitachi's automated cell culture equipment for cell therapy and gene therapy, and Axcelead DDP's wealth of experience in drug discovery research, offering to support the development of cell manufacturing processes for pharmaceutical companies and research institutes.

Hitachi and Axcelead, Inc., which has Axcelead DDP as the core company, have been working on joint development of solutions contributing to more efficient discovery of next-generation biopharmaceuticals\*, and this service is from one of such joint projects.

\* News Release on April 7, 2021 "Hitachi and Axcelead have agreed to start joint development of solutions contributing on more efficient creation of next-generation biopharmaceuticals"  
<https://www.hitachi.com/New/cnews/month/2021/04/210407.html>

### **<Background>**

Clinical application of cell therapy and gene therapy is becoming a reality, and commercial manufacturing of the cells by pharmaceutical companies is beginning. It requires the scale-up and high efficiency through mechanization and automation using automated cell culture equipment, etc. There are, however, technical challenges to maintain cell quality after the automation and scale-up cell culture since the quality of the cells is easy to change depending on the raw materials and culture conditions.

### **<Outline of Manufacturing Process Development Support Service>**

This service is provided to companies and research institutes that are considering the introduction and modification of automated cell culture equipment for the scale-up and further improvement of the quality of cells used for cell therapy and gene therapy products.

Upon the request of a customer, Hitachi conducts cell culture by its own automated cell culture equipment, and Axcelead DDP evaluates quality of the cells by analyzing various parameters according to cell types of customer's interest. Hitachi will explore the parameters that can be used in the equipment to produce stable and biologically equivalent cells based on the results of the Axcelead DDP, and optimize the culture process such as setting of the control system, culture vessel and medium. Hitachi and Axcelead DDP jointly offer the integrated manufacturing process development services including, for example, quality control, in vitro/in vivo pharmacological studies, IND (Investigational New Drug)-enabling studies, and consultation of non-clinical development strategy for IND/NDA (New Drug Application).

This service supports customers to reduce the time and cost for development of cell therapy and gene therapy products and optimize manufacturing.

Hitachi and Axcelead DDP aim to contribute to improving QoL (Quality of Life) through expanding clinical application of cell therapy and gene therapy by the joint manufacturing process development support service.

**Contacts**

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Enquiry Form:

[https://www8.hitachi.co.jp/inquiry/life/en/general/form.jsp?UM\\_QNo=5](https://www8.hitachi.co.jp/inquiry/life/en/general/form.jsp?UM_QNo=5)

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